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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/709,019 | 04/07/2004 | Nam T. Chao | 101896-0245 | 3018 |
| 21125 | 7590 | 11/02/2006 | EXAMINER | |
| NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604 | | | REIMERS, ANNETTE R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/709,019

Applicant(s)

CHAO ET AL.

Examiner

Annette R. Reimers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 7, 14, 30 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10, 13, 15-29, 31-34, 36, 37 and 39 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-10, 13, 15-29, 31-32, 34, 36-37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (FR 2,816,195), cited by applicant.

Taylor et al. disclose an implantable spinal cross-connector, 1, comprising a central portion, wherein at least one connector member can be integrally formed on a terminal end thereof, the at least one connector member, 2, having first and second opposed jaws, 25, adapted to seat a spinal rod therebetween, wherein at least one of the jaws being selectively movable between a first, open position wherein the first and second jaws are positioned a distance apart from one another and a second closed position wherein the first and second jaws are adapted to engage a spinal fixation element therebetween, and at least one of the jaws is integrally formed with the central portion and a locking mechanism, 3, having a shank that is receivable within a non-expandable bore, formed in the connector member, the locking mechanism being adapted to come into contact with each of the first and second jaws to selectively lock at least one of the first and second jaws in a fixed position (see figure 1)

The locking mechanism includes a non-eccentric head, 3a, formed on a proximal end of the shaft and a threaded portion that is effective to mate with the threaded portion of the bore formed in the second jaw (see figure 1). The non-expandable bore formed in the at least one connector member includes an enlarged proximal opening that is adapted to seat a non-eccentric head of the locking mechanism (see figure 1). The second jaw on the at least one connector member is pivotally mated to the first jaw, and wherein the non-eccentric head of the locking mechanism is effective to move the second jaw from the open position to the closed position when the head is disposed within the enlarged proximal opening of the non-expandable bore (see figure 1). In addition, the locking mechanism is adapted to pull the first and second jaws toward one another into the second closed position when the locking mechanism is advanced into the non-expandable bore (see figure 1). The first and second jaws define a substantially C-shaped recess therebetween (see figure 1). The first and second jaws include a slot, 21b, found therebetween and adapted to allow movement of the first and second jaws between the first open position and the second closed position (see figure 3 and 13).

The central portion comprises a substantially elongate member having an adjustable length (see figure 1). The substantially elongate member is formed from first and second transverse members, 6 and 5, that are slidably matable to one another (see figure 1). The first transverse member, 6, includes a female mating element and the second transverse member, 5, includes a male mating element that is adapted to be received by the female mating element (see figure 1). A central locking mechanism, 13, for locking the first and second transverse members at a fixed position with respect to

one another. In addition, the first and second transverse members are angularly adjustable with respect to one another along the longitudinal axis of the spinal cross-connector and are capable of being positioned at an angle of about 20 ° with respect to the longitudinal axis of the spinal cross-connector (see figure 1).

The central portion includes first and second transverse members that are connected to one another by a central clamp, 12, that allows angular adjustment of the first and second transverse members with respect to one another along a longitudinal axis of the spinal cross-connector (see figure 1). In addition, the central locking mechanism is formed in the central clamp for locking the first and second transverse members in a fixed position with respect to one another (see figure 1).

The central locking mechanism extends through the central clamp and each of the first and second transverse members is adapted to engage and close the central clamp, thereby locking the first and second transverse members therebetween (see figure 1). The at least one connector member includes a bend zone, 21b, formed between the connector member and the central portion to allow angular movement of the connector member with respect to the central portion (see figure 1).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Taylor et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read

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on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claims 1-2, 5-6, 8, 13, 18-22, 24-29, 31-32, 34, 36-37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Duff (US Patent Number 4,611,582), cited by applicant.

Duff discloses an implantable spinal cross-connector, 10, comprising a central portion, wherein at least one connector member can be integrally formed on a terminal end thereof, the at least one connector member, 20, having first and second opposed jaws, 40, adapted to seat a spinal rod therebetween, wherein at least one of the jaws being selectively movable between a first, open position wherein the first and second jaws are positioned a distance apart from one another and a second closed position wherein the first and second jaws are adapted to engage a spinal fixation element therebetween, and a locking mechanism, 48, having a shank that is receivable within a non-expandable bore, formed in the connector member, the locking mechanism being adapted to come into contact with each of the first and second jaws to selectively lock at least one of the first and second jaws in a fixed position (see figures 1 and 5) (see also figure 2, column 4, lines 26-29 and 57-68 and column 5, 1-3).

The locking mechanism includes a non-eccentric head, 52, formed on a proximal end of the shaft and a threaded portion, 48, that is effective to mate with the threaded portion of the bore formed in the second jaw (see figures 1 and 5). The second jaw on

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the at least one connector member is pivotally mated to the first jaw (see figures 1 and 5). In addition, the locking mechanism is adapted to pull the first and second jaws toward one another into the second closed position when the locking mechanism is advanced into the non-expandable bore (see figures 1 and 5) (see also figure 2, column 4, lines 26-29 and 57-68 and column 5, 1-3). The first and second jaws define a substantially C-shaped recess therebetween (see figures 1 and 5).

The central portion comprises a substantially elongate member having an adjustable length (see figures 1 and 5). The substantially elongate member is formed from first and second transverse members, 34 and 29, that are slidably matable to one another (see figure 1). The first transverse member, 34, includes a female mating element and the second transverse member, 29, includes a male mating element that is adapted to be received by the female mating element (see figure 1). A central locking mechanism, 34, for locking the first and second transverse members at a fixed position with respect to one another. In addition, the first and second transverse members are angularly adjustable with respect to one another along the longitudinal axis of the spinal cross-connector (see figures 1 and 5).

The central portion includes first and second transverse members that are connected to one another by a central clamp, 37, that allows angular adjustment of the first and second transverse members with respect to one another along a longitudinal axis of the spinal cross-connector (see figures 1 and 5). In addition, the central locking mechanism is formed in the central clamp for locking the first and second transverse members in a fixed position with respect to one another (see figures 1 and 5).

The central locking mechanism extends through the central clamp and each of the first and second transverse members is adapted to engage and close the central clamp, thereby locking the first and second transverse members therebetween (see figures 1 and 5). The at least one connector member includes a bend zone formed between the connector member and the central portion to allow angular movement of the connector member with respect to the central portion (see figures 1 and 5).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Duff, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (FR 2,816,195), as cited by applicant.

Taylor et al. disclose the claimed invention except for the clamping surface of the jaw members comprising a series of ridges device. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device of Taylor et al. with the clamping surface of the jaw members comprising a series of ridges device, since applicant has not disclosed that the clamping surface of the jaw members comprising a series of ridges solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a more secure form of screwing an object into a hole and for clamping an object. In re Dailey and Eilers, 149 USPQ 47 (1966). In addition, it appears that the invention would perform equally well with the clamping surface of the jaw members not comprising a series of ridges device

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duff (US Patent Number 4,611,582), as cited by applicant.

Duff discloses the claimed invention except for the clamping surface of the jaw members comprising a series of ridges device. It would have been an obvious matter of

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design choice to one skilled in the art at the time the invention was made to construct the device of Duff with the clamping surface of the jaw members comprising a series of ridges device, since applicant has not disclosed that the clamping surface of the jaw members comprising a series of ridges solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a more secure form of screwing an object into a hole and for clamping an object. In re Dailey and Eilers, 149 USPQ 47 (1966). In addition, it appears that the invention would perform equally well with the clamping surface of the jaw members not comprising a series of ridges device.

Allowable Subject Matter

Claims 11 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed on August 21, 2006 have been fully considered, but they are not persuasive. In response to applicant's argument that Taylor and Duff each fail to teach or suggest a connector member having at least one jaw integrally formed with the central portion or at least one connector member integrally formed on a terminal end of an elongate member, it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which

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a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Moreover, it has been held that forming in one piece an article, which has formerly been formed in two pieces, and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

In response to applicant's argument that Duff fails to teach or suggest the first and second opposed jaws include a bore formed therein, and that a threaded locking mechanism mates with a threaded portion of the bore in the second jaw to move at least one of the first and second jaws toward one another into a closed position, it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Moreover, as stated above, at least one of the jaws being selectively movable between a first, open position wherein the first and second jaws are positioned a distance apart from one another and a second closed position wherein the first and second jaws are adapted to engage a spinal fixation element therebetween, and a locking mechanism, 48, having a shank that is receivable within a non-expandable bore, formed in the connector member, the locking mechanism being adapted to come into contact with each of the first and second

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jaws to selectively lock at least one of the first and second jaws in a fixed position (see figures 1 and 5) (see also figure 2, column 4, lines 26-29 and 57-68 and column 5, 1-3).

The locking mechanism includes a non-eccentric head, 52, formed on a proximal end of the shaft and a threaded portion, 48, that is effective to mate with the threaded portion of the bore formed in the second jaw (see figures 1 and 5). The second jaw on the at least one connector member is pivotally mated to the first jaw (see figures 1 and 5). In addition, the locking mechanism is adapted to pull the first and second jaws toward one another into the second closed position when the locking mechanism is advanced into the non-expandable bore (see figures 1 and 5) (see also figure 2, column 4, lines 26-29 and 57-68 and column 5, 1-3).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER